UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,922	04/05/2001	David E. Comings	1954-332	3812

6449 7590 03/12/2002

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/825,922	COMINGS, DAVID E.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/6/01; 8/7/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-15, drawn to a method of determining whether a subject is at risk for ADHD by genotyping TPH, PNMT, ADOA2A, NOX3 or NAT1, classified in class 435, subclass 6.

   II. Claims 16-30, drawn to a method of determining whether a subject is at risk for ODD by genotyping HTR2A, PNMT or CD8, classified in class 435, subclass 6.

   III. Claims 31-45, drawn to methods of determining whether a subject is at risk for CD by genotyping HTR2A, GABBR1, ADOA2A, GRIN2B, NAT1, CCK, CYP, ESR, or CD8, classified in class 435, subclass 6.

   IV. Claims 46-48, drawn to screening drugs by measuring protein activity, classified in class 436, subclass 501.

   V. Claim 49, drawn to a method of treating a subject for ADHD by administering a nucleic acid, classified in class 514, subclass 44.

   VI. Claim 50, drawn to a method of treating a subject for OCC by administering a nucleic acid, classified in class 514, subclass 44.

   VII. Claim 51, drawn to a method of treating a subject for CD by administering a nucleic acid, classified in class 514, subclass 44.

   VIII. Claim 52, drawn to a method of treating a subject for ADHD by administering a protein, classified in class 514, subclass 2.

IX. Claim 53, drawn to a method of treating a subject for OCC by administering a protein, classified in class 514, subclass 2.

X. Claim 54, drawn to a method of treating a subject for CD by administering a protein, classified in class 514, subclass 2.

Restriction Requirement Applicable to All Groups:

2. The claims are drawn to detecting diseases, screening for drugs, or treating diseases using distinct gene sequences. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity.

A restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04).

The claims contains numerous individual, independent and distinct nucleotide sequences in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. 121 as outlined in 1192 O.G. 68 (November 19, 1996).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of

35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

The methods for detection of a disease using distinct gene sequences are patenably distinct methods. A method for determining whether a subject's genome comprises a non-wild-type allele from TPH is not obvious over a method of determining whether a subject's genome comprises a non-wild-type allele from PNMT, for example. Similarly, a method of screening for drug candidates for the distinct genes will be distinct. A drug which affects HTR2A would not be obvious over a drug which affects CD8. Finally, a method of treating a disease with one gene would not be obvious over each of the other gene. These methods are presumably patentably distinct sequences and each would hold a patent individually.

Should applicant traverse on the ground that the methods involving different nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Group I-X are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps.

As explained in the restriction to a single gene, the methods using different genes are distinct. The method of Group I is directed to detecting ADHD, Group II is for detecting ODD and finally Group III is directed to detecting CD using nucleic acids. Each of these methods use different genes for detecting. The methods of screening for drugs rely upon the protein levels as opposed to the nucleic acids. Finally the methods of treating use both proteins and nucleic acids. These methods rely upon different genes which are not obvious over one another. Therefore the methods are distinct over one another.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg
March 11, 2002

C. Dessau
CHANTAE DESSAU
PATENT ANALYST